

Notice of Allowability

Application No.

10/817,577

Examiner

Lakshmi S. Channavajjala

Applicant(s)

THOSAR ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6-7-06.
2. ☒ The allowed claim(s) is/are 1-5,7,9,11-17,20-24,26-37,45-47,57,73,77 and 78.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 8-18-06.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Anada
Lakshmi Channavajjala
Examiner
AU 1615

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Schuh on 8-18-08.

In the claims:

Claim 1, line 5, insert the word "microns" after "25"

Claim 57, line 1, replace "The method" with "A method"

Claim 57, line 5, after "treatment", insert "and wherein the said condition or disorder is selected from the group consisting of heart failure, hypertension, edema associated with liver insufficiency and post-myocardial infarction"

Cancel claim 58-61

Claim 73, line 2 delete "substantially" and on line 3 replace "about 11 minutes" with "6 minutes 16 second to 10 minutes 30 seconds"

Cancel claims 74-76.

In claim 77, line 2 delete the word "substantially"

In claim 78, line 2 delete the word "substantially"

In the specification:

On page 1, before line 1, insert the following priority data:

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"This is a continuation of application Serial No. 10/289,025 filed on November 6, 2002, now U.S. Patent NO. 6,863,902, which is a continuation of application Serial No. 10/100,930 filed on March 19, 2002, now U.S. Patent No. 6,534,093, which is a continuation of application Serial No. 09/456,614 filed on December 8, 1999, now U.S. Patent No. 6,410,054, which claims priority from United States Provisional application Serial No. 60/111,646 filed on December 9, 1998, now abandoned.

The following is an examiner's statement of reasons for allowance:

Instant claims are directed to pharmaceutical compositions comprising eplerenone with a D90 particle size of 25 microns to 400 microns. The advantage of pharmaceutical compositions comprising claimed particle size of eplerenone has not been recognized in the prior art. Applicants previously (parent application 09/456,614) established that the in vitro dissolution as well as the bioavailability of eplerenone is superior over the claimed range of particle sizes.

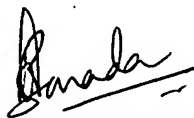
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
August 21, 2006